

1 JOHN J. POWERS (State Bar No. 145623)  
2 BENJAMIN J. HOLL (State Bar No. 200630)  
3 DRINKER BIDDLE & REATH LLP  
4 50 Fremont Street, 20th Floor  
5 San Francisco, CA 94105-2235  
6 Telephone: (415) 591-7500  
7 Facsimile: (415) 591-7510  
8 Email: john.powers@dbr.com  
9 benjamin.holl@dbr.com

10 Attorneys for Defendant  
11 ORTHO-MCNEIL-JANSSEN  
12 PHARMACEUTICALS, INC.

13 UNITED STATES DISTRICT COURT  
14 NORTHERN DISTRICT OF CALIFORNIA  
15 OAKLAND DIVISION

16 KIM CHANNING on behalf of herself as  
17 an heir at law of ELGA IDA HINDIN and  
18 as Executor of the Estate and/or Successor  
19 in Interest of ELGA IDA HINDIN;  
20 JENNIFER LYNN RICHARDS;  
21 JEFFFREY PAUL HINDIN and  
22 GERALDINE G. HINDIN,

23 Plaintiffs,

24 v.

25 JOHNSON & JOHNSON; ORTHO-  
26 MCNEIL PHARMACEUTICAL, INC.;  
27 JOHNSON & JOHNSON  
28 PHARMACEUTICAL RESEARCH  
DEVELOPMENT, LLC,

Defendants.

Case No. CV 08 2913 SBA

**ANSWER OF ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC. TO  
PLAINTIFFS' WRONGFUL DEATH  
COMPLAINT AND JURY DEMAND**

29 COMES NOW Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI"),  
30 named in the Complaint as Ortho-McNeil Pharmaceutical, Inc. ("OMP"), now known as OMJPI,  
31 and, in answer to Plaintiffs KIM CHANNING; JENNIFER LYNN RICHARDS; JEFFFREY  
32 PAUL HINDIN and GERALDINE G. HINDIN ("Plaintiffs") Wrongful Death Complaint  
33 ("Plaintiffs' Complaint") denies and alleges as follows.

1 Defendant denies each and every allegation, statement, matter and thing contained in  
2 Plaintiffs' Complaint except as is hereinafter expressly admitted or alleged.

3 **INTRODUCTION**

4 1. Defendant admits that levofloxacin is a fluoroquinolone, but denies the remaining  
5 allegations in paragraph 1 of Plaintiffs' Complaint.

6 2. Defendant admits that Defendant OMP, now known as OMJPI, marketed  
7 levofloxacin in the United States until December 31, 2007, when all assets of OMP were  
8 transferred to OMJPI, which now markets levofloxacin in the United States, but denies the  
9 remaining allegations in paragraph 2 of Plaintiffs' Complaint.

10 3. Defendant admits that levofloxacin was approved by the FDA for its labeled uses,  
11 but denies the remaining allegations in paragraph 3 of Plaintiffs' Complaint.

12 4. Defendant denies the allegations in paragraph 4 of Plaintiffs' Complaint.

13 5. Defendant denies the allegations in paragraph 5 of Plaintiffs' Complaint.

14 6. Defendant is without knowledge or information sufficient to admit or deny the  
15 allegations that Elga Ida Hindin took Levaquin®, but otherwise denies the allegations in  
16 paragraph 6 of Plaintiffs' Complaint

17 7. Defendant states that paragraph 7 of the Complaint requires no response as the  
18 Complaint speaks for itself, but to the extent a response is required, it denies the allegations in  
19 paragraph 7 of Plaintiffs' Complaint.

20 **JURISDICTION**

21 8. Defendant admits the allegations in paragraph 8 of Plaintiffs' Complaint.

22 9. Defendant admits the allegations in paragraph 9 of Plaintiffs' Complaint.

23 10. Defendant is without knowledge or information sufficient to admit or deny the  
24 allegations in paragraph 10 of Plaintiffs' Complaint.

25 11. Defendant is without knowledge or information sufficient to admit or deny the  
26 allegations in paragraph 11 of Plaintiffs' Complaint.

27 12. Defendant is without knowledge or information sufficient to admit or deny the  
28 allegations in paragraph 12 of Plaintiffs' Complaint.

1 13. Defendant is without knowledge or information sufficient to admit or deny the  
2 allegations in paragraph 13 of Plaintiffs' Complaint.

3 14. Defendant admits the allegations in paragraph 14 of Plaintiffs' Complaint.

4 15. Defendant denies the allegations in paragraph 15 of Plaintiffs' Complaint as stated.  
5 Defendant states that OMJPI is a Pennsylvania corporation with its principal place of business in  
6 Titusville, New Jersey.

7 16. Defendant denies the allegations in paragraph 16 of Plaintiffs' Complaint, except  
8 to admit that Johnson & Johnson Pharmaceutical Research & Development, LLC ("J&JPRD")  
9 did research, development and testing on Levaquin®, and that Levaquin® was a product of OMP,  
10 now known as OMJPI, and is now a product of OMJPI.

11 17. Defendant denies the allegations in paragraph 17 of Plaintiffs' Complaint as stated.

12 **FACTS**

13 18. In response to the allegations in paragraph 18 of Plaintiffs' Complaint, Defendant  
14 denies the allegations as stated as incomplete, and states that levofloxacin is a synthetic broad  
15 spectrum antibacterial agent for oral and intravenous administration. The approved uses of  
16 Levaquin® are stated in the prescribing information in the package insert.

17 19. Defendant denies the allegations in paragraph 19 of Plaintiffs' Complaint.

18 20. Defendant denies the allegations in paragraph 20 of Plaintiffs' Complaint.

19 21. Defendant denies the allegations in paragraph 21 of Plaintiffs' Complaint, as  
20 stated, but admits that different fluoroquinolones may differ in safety profile.

21 22. Defendant denies the allegations in paragraph 22 of Plaintiffs' Complaint.

22 23. In response to the allegations in paragraph 23 of Plaintiffs' Complaint, Defendant  
23 admits that Levaquin® was developed by Daiichi, that Johnson & Johnson ("J&J") has a  
24 licensing agreement with Daiichi, that OMP, now known as OMJPI, manufactured and marketed  
25 and now OMJPI manufactures and markets Levaquin® pursuant to a licensing agreement, but  
26 denies the remaining allegations of paragraph 23 of Plaintiffs' Complaint.

27 24. Defendant denies the allegations in paragraph 24 of Plaintiffs' Complaint.

28 25. Defendant denies the allegations in paragraph 25 of Plaintiffs' Complaint.

26. Defendant is without knowledge or information sufficient to admit or deny the allegations in paragraph 26 of Plaintiffs' Complaint.

27. Defendant denies the allegations in paragraph 27 of Plaintiffs' Complaint as stated. The chemical composition of Levofloxacin is stated in the prescribing information in the package insert.

28. Defendant denies the allegations in paragraph 28 of Plaintiffs' Complaint.

29. Defendant denies the allegations in paragraph 29 of Plaintiffs' Complaint.

30. Defendant denies the allegations in paragraph 30 of Plaintiffs' Complaint as stated. The allegations are an incomplete description of the scientific knowledge regarding fluoroquinolones. Defendant states that the scientific literature and studies regarding fluoroquinolones speak for themselves. Defendant further states that the scientific literature and reported research on Levaquin® form part of the basis of the marketing of the drug and the approval of it by the FDA, pursuant to the prescribing information.

31. Defendant denies the allegations in paragraph 31 of Plaintiffs' Complaint as stated. The allegations are an incomplete description of the scientific knowledge regarding fluoroquinolones. Defendant states that the scientific literature and studies regarding fluoroquinolones speak for themselves. Defendant further states that the scientific literature and reported research on Levaquin® form part of the basis of the marketing of the drug and the approval of it by the FDA, pursuant to the prescribing information.

32. Defendant denies the allegations in paragraph 32 of Plaintiffs' Complaint.

33. Defendant denies the allegations in paragraph 33 of Plaintiffs' Complaint.

34. Defendant denies the allegations in paragraph 34 of Plaintiffs' Complaint, including each and every subparagraph (a) through (gg).

**FIRST CAUSE OF ACTION**  
**STRICT PRODUCTS LIABILITY – DEFECTIVE MANUFACTURING**

35. In response to the allegations in paragraph 35 of Plaintiffs' Complaint, Defendant restates, realleges and incorporates by reference paragraphs 1 through 34 of its answer to Plaintiffs' Complaint.

36. Defendant denies the allegations in paragraph 36 of Plaintiffs' Complaint, except to admit that J&JPRD did research, development and testing on Levaquin®, and that Levaquin® was a product of OMP, now known as OMJPI, and is now a product of OMJPI.

37. Defendant denies the allegations in paragraph 37 of Plaintiffs' Complaint as stated.

38. Defendant denies the allegations in paragraph 38 of Plaintiffs' Complaint.

39. In response to the allegations in paragraph 39 of Plaintiffs' Complaint, Defendant is without sufficient information to admit or deny the allegation that Elga Ida Hindin used Levaquin® in the manner for which it was intended, and therefore denies the same. Defendant denies the remaining allegations in paragraph 39 of Plaintiffs' Complaint.

40. Defendant denies the allegations in paragraph 40 of Plaintiffs' Complaint.

41. In response to the allegations in paragraph 41 of Plaintiffs' Complaint, Defendant is without sufficient information to admit or deny the allegation that Elga Ida Hindin used Levaquin® in the manner for which it was intended, and therefore denies the same. Defendant denies the remaining allegations in paragraph 41 of Plaintiffs' Complaint.

42. Defendant denies the allegations in paragraph 42 of Plaintiffs' Complaint.

43. Defendant denies the allegations in paragraph 43 of Plaintiffs' Complaint.

44. Defendant denies the allegations in paragraph 44 of Plaintiffs' Complaint.

45. Defendant denies the allegations in paragraph 45 of Plaintiffs' Complaint.

46. Defendant denies the allegations in paragraph 46 of Plaintiffs' Complaint.

47. Defendant denies the allegations in paragraph 47 of Plaintiffs' Complaint.

**SECOND CAUSE OF ACTION**  
**STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

48. In response to the allegations in paragraph 48 of Plaintiffs' Complaint, Defendant restates, realleges and incorporates by reference paragraphs 1 through 47 of its answer to Plaintiffs' Complaint.

49. Defendant denies the allegations in paragraph 49 of Plaintiffs' Complaint, except to admit that J&JPRD did research, development and testing on Levaquin®, and that Levaquin® was a product of OMP, now known as OMJPI, and is now a product of OMJPI.

1 50. Defendant denies the allegations in paragraph 50 of Plaintiffs' Complaint.

2 51. Defendant denies the allegations in paragraph 51 of Plaintiffs' Complaint.

3 52. Defendant denies the allegations in paragraph 52 of Plaintiffs' Complaint.

4 **THIRD CAUSE OF ACTION**  
5 **STRICT PRODUCTS LIABILITY -DEFECT DUE TO INADEQUATE WARNING**

6 53. In response to the allegations in paragraph 53 of Plaintiffs' Complaint, Defendant  
7 restates, realleges and incorporates by reference paragraphs 1 through 52 of its answer to  
8 Plaintiffs' Complaint.

9 54. Defendant denies the allegations in paragraph 54 of Plaintiffs' Complaint, except  
10 to admit that J&JPRD did research, development and testing on Levaquin®, and that Levaquin®  
11 was a product of OMP, now known as OMJPI, and is now a product of OMJPI.

12 55. Defendant denies the allegations in paragraph 55 of Plaintiffs' Complaint.

13 56. Defendant denies the allegations in paragraph 56 of Plaintiffs' Complaint.

14 57. Defendant denies the allegations in paragraph 57 of Plaintiffs' Complaint.

15 58. Defendant denies the allegations in paragraph 58 of Plaintiffs' Complaint.

16 **FOURTH CAUSE OF ACTION**  
17 **NEGLIGENCE**

18 59. In response to the allegations in paragraph 59 of Plaintiffs' Complaint, Defendant  
19 restates, realleges and incorporates by reference paragraphs 1 through 59 of its answer to  
20 Plaintiffs' Complaint.

21 60. Defendant states that it was subject only to those duties imposed by applicable  
22 law, and denies the allegations of paragraph 60 of Plaintiffs' Complaint. Defendant denies that  
23 Levaquin® was defective or dangerous.

24 61. Defendant denies the allegations in paragraph 61 of Plaintiffs' Complaint.

25 62. Defendant denies the allegations in paragraph 62 of Plaintiffs' Complaint.

26 63. Defendant denies the allegations in paragraph 63 of Plaintiffs' Complaint.

27 64. Defendant denies the allegations in paragraph 64 of Plaintiffs' Complaint.

28 65. Defendant denies the allegations in paragraph 65 of Plaintiffs' Complaint.

**FIFTH CAUSE OF ACTION**  
**BREACH OF EXPRESS WARRANTY**

66. In response to the allegations in paragraph 66 of Plaintiffs' Complaint, Defendant restates, realleges and incorporates by reference paragraphs 1 through 65 of its answer to Plaintiffs' Complaint.

67. Defendant denies the allegations in paragraph 67 of Plaintiffs' Complaint.

68. Defendant denies the allegations in paragraph 68 of Plaintiffs' Complaint.

69. Defendant denies the allegations in paragraph 69 of Plaintiffs' Complaint and denies that it extended any express warranties to Plaintiff.

**SIXTH CAUSE OF ACTION**  
**BREACH OF IMPLIED WARRANTY**

70. In response to the allegations in paragraph 70 of Plaintiffs' Complaint, Defendant restates and incorporates by reference paragraphs 1 through 69 of its answer to Plaintiffs' Complaint.

71. Defendant denies the allegations in paragraph 71 of Plaintiffs' Complaint, except to admit that J&JPRD did research, development and testing on Levaquin®, and that Levaquin® was a product of OMP, now known as OMJPI, and is now a product of OMJPI. Answering further, Defendant states that the allegations contained therein call for a legal conclusion to which no response is necessary, but responding further, Defendant denies those allegations to the extent they seek to impose obligations on Defendant beyond those required by law.

72. In response to the allegations in paragraph 72 of Plaintiffs' Complaint, Defendant is without sufficient information to admit or deny the allegations of this paragraph and therefore denies the same.

73. Defendant denies the allegations in paragraph 73 of Plaintiffs' Complaint.

74. Defendant denies the allegations in paragraph 74 of Plaintiffs' Complaint, and denies that it breached any warranties, if any, extended by operation of law.

**SEVENTH CAUSE OF ACTION**  
**NEGLIGENT MISREPRESENTATION**

75. In response to the allegations in paragraph 75 of Plaintiffs' Complaint, Defendant



1 restates and incorporates by reference paragraphs 1 through 75 of its answer to Plaintiffs'  
2 Complaint.

3 76. Defendant denies the allegations in paragraph 76 of Plaintiffs' Complaint.

4 77. Defendant denies the allegations in paragraph 77 of Plaintiffs' Complaint.

5 78. In response to the allegations in paragraph 78 of Plaintiffs' Complaint, Defendant  
6 is without sufficient information to admit or deny the allegations of this paragraph and therefore  
7 denies the same.

8 79. Defendant denies the allegations in paragraph 79 of Plaintiffs' Complaint.

9 **EIGHTH CAUSE OF ACTION**  
10 **FRAUD**

11 80. In response to the allegations in paragraph 80 of Plaintiffs' Complaint, Defendant  
12 restates and incorporates by reference paragraphs 1 through 79 of its answer to Plaintiffs'  
13 Complaint.

14 81. Defendant denies the allegations in paragraph 81 of Plaintiffs' Complaint.

15 82. Defendant denies the allegations in paragraph 82 of Plaintiffs' Complaint and  
16 states that serious as well as minor side effects, including tendon rupture, have been reported in  
17 conjunction with use of all quinolones, including Levaquin®. Defendant further states that the  
18 FDA-approved prescribing information for Levaquin® has at all times contained the appropriate  
19 information for the prescribing physician.

20 83. Defendant denies the allegations in paragraph 83 of Plaintiffs' Complaint.

21 84. Defendant denies the allegations in paragraph 84 of Plaintiffs' Complaint,  
22 including each and every subparagraph (a) through (j).

23 85. Defendant denies the allegations in paragraph 85 of Plaintiffs' Complaint.

24 86. Defendant denies the allegations in paragraph 86 of Plaintiffs' Complaint.

25 87. Defendant denies the allegations in paragraph 87 of Plaintiffs' Complaint.

26 88. Defendant denies the allegations in paragraph 88 of Plaintiffs' Complaint.

27 89. Defendant denies the allegations in paragraph 89 of Plaintiffs' Complaint.

28 90. Defendant denies the allegations in paragraph 90 of Plaintiffs' Complaint.



91. Defendant denies the allegations in paragraph 91 of Plaintiffs' Complaint.
92. Defendant denies the allegations in paragraph 92 of Plaintiffs' Complaint.
93. Defendant denies the allegations in paragraph 93 of Plaintiffs' Complaint.
94. Defendant denies the allegations in paragraph 94 of Plaintiffs' Complaint.
95. Defendant denies the allegations in paragraph 95 of Plaintiffs' Complaint.
96. Defendant denies the allegations in paragraph 96 of Plaintiffs' Complaint.
97. Defendant denies the allegations in paragraph 97 of Plaintiffs' Complaint.
98. Defendant denies the allegations in paragraph 98 of Plaintiffs' Complaint.
99. Defendant denies the allegations in paragraph 99 of Plaintiffs' Complaint.
100. Defendant denies the allegations in paragraph 100 of Plaintiffs' Complaint.
101. Defendant denies the allegations in paragraph 101 of Plaintiffs' Complaint.

**AFFIRMATIVE DEFENSES**

AS FURTHER AND SEPARATE AFFIRMATIVE DEFENSES, the answering Defendant alleges as to Plaintiffs:

**FIRST AFFIRMATIVE RELIEF**

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

**SECOND AFFIRMATIVE RELIEF**

Plaintiffs' claims are barred by the applicable statute of limitations.

**THIRD AFFIRMATIVE RELIEF**

Any purported injuries of which Plaintiffs complain in the Complaint were not caused by Defendant, but were caused by the actions or inactions of a person or persons or entities over whom Defendant had neither control nor right of control. Plaintiffs' recovery should be barred or, at a minimum, should be reduced or apportioned in accordance with the principles of comparative negligence and the Joint Tortfeasor Contribution Act.

**FOURTH AFFIRMATIVE RELIEF**

Plaintiffs' alleged damages or injuries, if any, were caused in whole or in part by the Decedent's unreasonable, unforeseeable, inappropriate, and/or improper use of the product.

**FIFTH AFFIRMATIVE RELIEF**

Plaintiffs have failed to mitigate damages, if any.

**SIXTH AFFIRMATIVE RELIEF**

The products identified in the Complaint were approved by the FDA and other government authorities and this answering Defendant acted at all times in compliance with the rules and regulations of the FDA and other governmental authorities.

**SEVENTH AFFIRMATIVE RELIEF**

Levaquin® (levofloxacin) is a prescription medical product. It falls under the auspices of the Food, Drug, and Cosmetic Act and regulations promulgated by the federal Food and Drug Administration, and all causes of action are therefore preempted by Federal Law. See 21 U.S.C. §§ 301 to 399, 71 Fed. Reg. 3922 (January 24, 2006). Plaintiffs' cause of actions against Defendant related to Levaquin® (levofloxacin), therefore, fail to state a claim upon which relief can be granted; such claim, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

**EIGHTH AFFIRMATIVE RELIEF**

The products identified in the Complaint were in conformity with the state of the art and/or the state of scientific knowledge at the relevant times involved.

**NINTH AFFIRMATIVE RELIEF**

Plaintiffs' claims are barred because the benefits relevant to the product outweighed the risks.

**TENTH AFFIRMATIVE RELIEF**

Plaintiffs' claims are barred by the doctrines of informed consent, release, and waiver.

**ELEVENTH AFFIRMATIVE RELIEF**

Plaintiffs' claims are barred by the learned intermediary doctrine.

**TWELFTH AFFIRMATIVE RELIEF**

Plaintiffs' claims are barred by the Decedent's assumption of the risk.

**THIRTEENTH AFFIRMATIVE RELIEF**

Plaintiffs' claims are barred by the doctrine of laches and/or estoppel.

**FOURTEENTH AFFIRMATIVE RELIEF**

Plaintiffs' injuries are the result of a superseding cause.

**FIFTEENTH AFFIRMATIVE RELIEF**

Plaintiffs have failed to allege fraud, concealment, or misrepresentation with sufficient particularity.

**SIXTEENTH AFFIRMATIVE RELIEF**

No privity of contract existed between Plaintiffs and this answering Defendant.

**SEVENTEENTH AFFIRMATIVE RELIEF**

Affirmatively and alternatively, this Defendant pleads the application of Comment (k) to the Restatement of Torts (Second) Section 402A and Restatement (Third) Torts; Products Liability Section 6.

**EIGHTEENTH AFFIRMATIVE RELIEF**

To the extent not stated above, Defendant raises all affirmative defenses available under the law of the forum in which each respective claim arose.

**NINETEENTH AFFIRMATIVE RELIEF**

This Defendant specifically reserves the right to present other and further defenses after further discovery and investigation herein.

Wherefore, Defendant prays that Plaintiffs take nothing by way of their Complaint, and that judgment for costs, reasonable attorneys' fees, and such other relief as the Court may deem proper be awarded to Defendant.

1 Dated: August 22, 2008

Respectfully submitted,

2 DRINKER BIDDLE & REATH LLP

3  
4 By: /s/ John J. Powers

5 JOHN J. POWERS (SBN 145623)  
6 BENJAMIN J. HOLL (SBN 200630)

7 DRINKER BIDDLE & REATH LLP  
8 50 Fremont Street, 20th Floor  
9 San Francisco, CA 94105-2235  
Telephone: (415) 591-7500  
Facsimile: (415) 591-7510  
Email: john.powers@dbr.com  
benjamin.holl@dbr.com

10 Attorneys for Defendant  
11 ORTHO-MCNEIL-JANSSEN  
12 PHARMACEUTICALS, INC.

13 **DEMAND FOR JURY TRIAL**

14 Defendant demands trial by jury of all issues triable by a jury pursuant to Federal Rule of  
15 Civil Procedure 38 and Civil Local Rule 3-6.

16 Dated: August 22, 2008

Respectfully submitted,

17 DRINKER BIDDLE & REATH LLP

18  
19 By: /s/ John J. Powers

20 JOHN J. POWERS (SBN 145623)  
21 BENJAMIN J. HOLL (SBN 200630)

22 DRINKER BIDDLE & REATH LLP  
23 50 Fremont Street, 20th Floor  
24 San Francisco, CA 94105-2235  
Telephone: (415) 591-7500  
Facsimile: (415) 591-7510  
Email: john.powers@dbr.com  
benjamin.holl@dbr.com

25 Attorneys for Defendant  
26 ORTHO-MCNEIL-JANSSEN  
27 PHARMACEUTICALS, INC.  
28